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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,743	05/09/2001	James Nolan	00-388-A	4067

7590

10/07/2005

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,743

Applicant(s)

NOLAN ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-16, 18-26, 28-31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 and 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 13-16, 18, 19, 25, 26, 28-31 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 28, 2005 has been entered.

Claims 1-4, 6-16, 18-26, 28-31, 33-35 are pending. Claims 8-12, 20-24 stand withdrawn for the reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-4, 6-7, 13-16, 18-19, 25-26, 28-31, 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banknieder et al US Patent 4,751,243 in view of York US Patent 4,600,717.

The scope of the instant claims is viewed given their broadest reasonable interpretation consistent with the specification. Accordingly, the claims are directed to methods of identifying a compound for treatment of wounds to skin or another external body surface in a diabetic animal, which also includes ophthalmic wounds. The method comprises producing a wound at a site of interest, expose the wound topically to a aldose reductase inhibitor, and assess the rate of wound healing. Claims 2 and 14 further require assessing the efficacy of another compound against the employed aldose reductase inhibitor.

Banknieder discloses methods of improving wound healing by administering an effective amount of tolerstat, which is an aldose reductase inhibitor compound to a patient. (abstract). Bankneider discloses methods of identifying the efficacy of tolerstat as a compound for healing wounds in diabetic rats against controlled subjects. (see col 2, line 13-col 3, line 20). Bankneider created a wound in diabetic animal models, treated

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the animals with controls, regular diet and tolerstat doses and subsequently determined that rats that were treated with had improved wound healing (see entire col 2-3; claims 1-5). The controls and regular diet of Bankneider's Group III meets the limitations of the instant claim 2 and 14 of comparing wounds in the presence of a test compound, because at least the instantly recited test compounds encompass the regular diet of Bankneider. Bankneider further claims methods of treating human with wounds from diabetes mellitus. Bankneider only fails to administer his aldose reductase inhibitor topically the wound and use punch biopsy to produce the wound.

York shows topical administration of aldose reductase inhibitors in suitable carrier system. York also shows effective treatment of ocular wounds in humans by administering various aldose reductase inhibitors also disclosed in his parent cases. (see abstract, col 1, lines 25-59; col 2, lines 1-67).

Accordingly, absence of showing unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to treat a wound in respective studied subjects by any known mechanism of producing a wound, such as punch biopsy, because the ordinary skill in the art would have expected to see the same results in any type of skin wound created on the skin.

In addition, it would have been also obvious to one of ordinary skill in the art at the time of invention to practice Banknieder's method by administering his aldose reductase inhibitor topically to a site of interest, because as shown by York, such compounds as aldose reductase inhibitors, are can provide their wound healing properties when administered topically. The ordinary skill in the art would have had a

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reasonable expectation of success because, as described by York, aldose reductase inhibitors provide their wound healing effects when administered topically.

3. Claims 1-4, 6-7, 13-16, 18-19, 25-26, 28-31, 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over York US Patent 4,600,717 in view of FDA Guideline No. 38, Guideline For Effective Evaluation of Topical/Otic Animal Drugs, revised Aug 21, 1984, Center for Veterinary Medicine. 8/21/1984, available at fda.gov/cvm/guidance/guideline38.htm. Last visited Sep 2005. ("Guideline No. 38") and Chen US Patent 6,232,341.

York shows topical administration of aldose reductase inhibitors in suitable carrier system. (abstract, col 2, lines 30-65). York also shows suggests effective treatment of ocular wounds in diabetic humans by administering various aldose reductase inhibitors. (see abstract, col 1, lines 20-59; col 2, lines 1-67). York fails to compare the efficacy of his compositions against other potentially useful agents.

Guideline No. 38 is merely used to show the standard for assessing topical efficacy of candidate drugs. Attention is drawn to section VIII-X, wherein the study format and appropriate control groups are recommended by the FDA to substantiate the efficacy results of any give drug. (see specifically Sec IX).

Chen is used as an example of the Guideline No. 38 in a clinical efficacy study. Chen shows the state of art as to methods of assessing the efficacy of topical therapeutic preparation in treating skin wound comprising creating a wound, applying the drug of interest randomly among animals, comparing the rate of healing and assessing the efficacy of the drug (see example 3, col 5-8). Chen does not teach the

use of his methodology on comparing the efficacy of topical agents against aldose reductase inhibitors in diabetic animals.

Nevertheless, it would have been obvious to one of ordinary skill in the art at the time of invention, to use compare aldose reductase inhibitors of York against other potential candidate agents by as described by Guideline No. 38 and exemplified by Chen's methodologies, because as taught by the Guideline No. 38 and Chen, such methods of comparative analysis is well practiced in the art for assessing the cutaneous effects of drugs on ulcer or burn wounds. The ordinary artisan would have had a reasonable expectation in observing positive results comparative results against aldose reductase inhibitors because they are proven to be effective as a wound-healing agent.

Conclusion

4. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER